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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,434	06/19/2001	Rudy A. Mazzocchi	723.020US1	9942

21186 7590 09/11/2003

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/11/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,434

Applicant(s)

MAZZOCCHI ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-14, 16, 17, 24, 25 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 24, 25, 32-39 and 44 is/are rejected.
- 7) ☒ Claim(s) 16, 17, 40-43, 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 7, 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-14, 37-39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt ('932).

Schmidt discloses a system comprising an elongate probe (200) including proximal and distal ends and having limitations within the ranges set forth in claim 1 (see col. 6, lines 60-65). The probe (200) has a substantially uniform cylindrical outer surface that is sized to be accepted within a trajectory guide device. It is noted that the trajectory guide device is not being positively claimed in the application claims. Rather, the recitation of the trajectory guide merely implies an intended use of the probe. The use of such guides is generally well known in the art, and the examiner maintains that the Schmidt probe may clearly be used with such a trajectory guide. Schmidt also

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discloses the use of titanium materials which are compatible with MR imaging (col. 2, lines 20-43 and col. 5, line 59). Figures 11 and 12 show a clip structure having substantially open and closed positions for grasping an aneurysm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (932) in view of the teaching of Gillies et al ('370).

Schmidt fails to specifically disclose an MR imaging device, although there is reference to the use of MR imaging.

Gillies et al disclose an MR imaging device using a microcoil arrangement (Figure 3) which can be utilized in surgical treatments for positioning instruments within a patient's skull (Figure 1). Such a system is advantageous in that it provides a clearer image and more specific positioning data than other prior art systems.

To have provided the Schmidt system with an MR imaging device, as taught by Gillies, to more accurately and safely locate the Schmidt et al device within the selected brain tissue would have been an obvious consideration for one of ordinary skill in the art.

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Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (932) in view of the teaching of Sheldon et al ('602).

Schmidt fails to disclose an entry device having securing mechanisms for securing the entry device to a skull and for securing a trajectory guide which is then used to introduce the probe portion to tissue.

As asserted previously, it is generally well known to use stereotactic devices for securing probes during surgery. Sheldon et al disclose one such stereotactic device which includes a first securing mechanism (10) to secure an entry device to the subject's skull, and a second securing mechanism (see the elements which allow for the vertical adjustment of the position of item 12 in figure 1) to secure the orientation of a trajectory guide (30). The trajectory guide is used to introduce a probe or probes to the desired treatment site.

To have provided the Schmidt system with a stereotactic frame and guide device as taught by Sheldon et al to allow for the safe and accurate placement of the probe within the desired treatment site would have been an obvious modification for one of ordinary skill in the art.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (932) in view of the teaching of Gillies et al ('370), and further in view of the teaching of Sheldon et al.

The combination of the Schmidt system with the Gillies et al MR imaging system has been addressed previously. In summary, Gillies et al teach that it is known to

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provide MR imaging means for visualizing the location and placement of brain probes, and such an imaging system would allow for the accurate placement of the Schmidt probe. However, there is no teaching of the particular entry device and securing mechanism.

Sheldon et al, as addressed previously, discloses a known stereotactic frame which includes first and second securing mechanisms and allows for the introduction of a probe, such as the Schmidt probe, through a trajectory device which is aptly secured to a patient's skull.

To have provided the Schmidt system, as modified by the teaching of Gillies et al, with an entry device having securing mechanisms for safely providing the probe to the desired tissue site would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sheldon et al.

Allowable Subject Matter

Claims 16, 17, 40-43, 45 and 46 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive.

Applicant contends that the Schmidt reference fails to disclose a distal portion of an aneurysm treatment device which is releasable to grasp about an aneurysm while a proximal portion of the device is disposed within a probe and the probe is accepted within the lumen of a trajectory guide device. It is the examiner's position that applicant's claims fail to positively recite the structure of the trajectory. Rather, the limitations involving the trajectory guide are merely indicative of an intended use. It is also the examiner's position that the Schmidt device would be capable of being used with such a trajectory guide device despite applicant's assertions to the contrary. It is applicant's assertion that in order to disengage the Schmidt applicator from the cantilever spring, the legs (140,160) must be moved laterally and such a lateral motion would be impossible if the legs were constrained by the guide tube which was, in turn, constrained by a trajectory guide device. While the examiner agrees that it appears a lateral motion is necessary, the examiner disagrees that such a motion would be impossible if a trajectory guide tube were being used. For instance, if the trajectory guide tube were sufficiently short (i.e. attached only at the proximal end of the probe) it would be possible to move the probe far enough to disengage the legs. Moreover, other analogous devices exist which require lateral motion to free a clip applicator while the clip applicator is within a probe which is within a guide tube (see US Patent No. 6,464,710 to Foster) thereby indicating such a release mechanism would work with a

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trajectory guide tube. Again, the examiner stresses that the trajectory guide tube is not positively recited and there are no specific structural features of the trajectory guide which bear patentable weight to the claims.

With regard to the 35 USC 103 rejections, applicant essentially reiterates the position that Schmidt fails to disclose the particular use of the device with a trajectory tube. The examiner maintains that the structure of the Schmidt reference anticipates the positively recited structure of the rejected claims and that the Schmidt device is fully capable of being used with a trajectory guide tube. Applicant also contends that the Schmidt device is intended for visually observed surgery. The examiner maintains that even if this were true, the Gillies et al reference teaches that it is known to provide intraoperative imaging of probes deployed for treating brain tissue, and that one of ordinary skill in the art would obviously use the Schmidt device in such an imaging procedure in view of the teaching of Gillies et al.

Conclusion

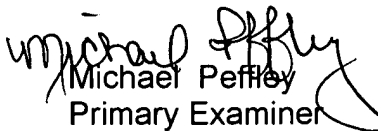
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Foster ('710) discloses a surgical clamp device very much analogous to the Schmidt device, and further teaches that the probe may be extended through a trajectory guide tube (see Figure 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
September 3, 2003